Appendix H. Evidence Tables and Overall Quality Ratings

Evidence Table H-1: Support

Evidence Table H-1a. Support trials

| **Author, yearCountryOverall Quality Rating** | **Eligibility Criteria** | **Exclusion Criteria** | **Number Screened/ Eligible/ Enrolled/ Analyzed** | **Age****Sex****Race** | **Intervention Type** |
| --- | --- | --- | --- | --- | --- |
| Allman, 19871 USGood | 18 years or olderPresence of a PU on sacrum, buttocks, trochanters, or backActivity expected to be limited to bed or chair in hospital for at least one weekPatient expected to live at least one week | Previous inclusion in trialSkin graft or flap planned for pressure sore within one week | NR/140/72/65 | Age (Mean): 67 yearsFemale: 58% Race: Black: 62% | Support: AF Beds |
| Branom, 20012USPoor | Admitted as inpatient to one of the two test sitesStage III or IV PUs on trunk or pelvisBedridden | NR | NR/NR/20/20 | Age (Mean):74 yearsFemale: NRRace: NR | Support: Support: Air Bed with Foam Overlay |
| Caley, 19943USPoor | Existing PULAL recommended for treatment by MD or enterostomal therapy nurse | NR | NR/NR/93/55(106 PUs. Results presented for PUs) | Age (Mean): 76 yearsFemale: 60% Race:Caucasian: 87%African American: 13% | Support: LAL Beds  |
| Clark, 1997 4UKFair | Over 65 years old Stage II, III, or IV PU greater than 2 cm2 in surface areaPU located on the sacrum or ischial tuberositiesAt moderate to high risk of developing further soresAble to sit for at least 2 hoursSerum albumin level of greater than 2.5 mg/dl Expected to remain in study for more than 7 days | PU greater than 15 cm2 | NR/33/33/25 | Age (Mean): 83 yearsFemale: 72% Race: NR | Support: AP Cushions |
| Day, 1993 5USPoor | Hospitalized18 years or older Stage II, III or IV PULife expectancy of at least one weekActivity limited to bed or chair during hospitalization | Previous study enrollmentExpected hospitalization less than 7 daysSkin graft or flap within 7 days of enrollment. | 118/83/83/83 | Age (Mean):76 yearsFemale: 58% Race: NR | Support: Air suspension |

| **Evidence Table 1a. Support Trials, continued** |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author, yearCountryOverall Quality Rating** | **Eligibility Criteria** | **Exclusion Criteria** | **Number Screened/ Eligible/ Enrolled/ Analyzed** | **Age****Sex****Race** | **Intervention Type** |
| Devine, 19956ScotlandFair | Patients admitted to Geriatric Unit PU of Stage II or above (on a five grade scale)  | NR | NR/NR/41/30 | Age (Mean): 83 yearsFemale: 59%Race: NR | Support: AP Beds |
| Evans, 2000 7Land, 20008UKGood | 65 years or older Stage III PU or stage II PU and one or more of the following: difficulty repositioning in bed and unable to tolerate at 30 degree tilt; unable to move in bed; in bed for more than 20 hours in 24 hours; weight greater than 108 kg and bed bound; or undergone spinal anesthetic | Spinal metastasesExudating wounds that may lead to hygiene or infection control problemsWeight greater than 250 kg | NR/NR/32/32 | Age (Mean):81 yearsFemale: 78% Race: NR | Support: AP Beds |
| Ferrell, 19939USGood | Stage II or higher PU (Shea scale) on trunk, buttocks or trochanters | Expected survival of less than one monthPrevious participation in studyPrevious or planned surgical excision of PU. | NR/NR/84/84 | Age (Mean):85 yearsFemale: 50% Race: NR | Support: LAL Beds |
| Groen, 199910HollandFair | 60 years or olderPU on truck classified as grade III or IV(article did describe grading system) | Severe or terminal illness | NR/NR/120/101  | Age (Mean): 83 yearsFemale: NRRace: NR | Support: Foam and Water Mattresses |
| Izutsu, 199811JapanPoor | Bedridden patients with decubitus  | Immunocompromised and patients with mycobacterial infections | NR/NR/31/31 | Age (Mean): 78 yearsFemale: 58% Race: NR | Support: Automatic Rolling Air Cushioned Bed  |
| Jackson, 198812USPoor | 18 years or older Stage III, IV, or V PURequired some form of pressure-relieving device | Renal disease; fluid restriction, dehydration, congestive heart failure/pulmonary edema; urinary incontinence (in which indwelling catheters were contraindicated) and severe diarrhea; daily treatments that required getting the patient into and out of the air-fluidized bed; patient inability to get into and out of bed without assistance; sensory deprivation; and poor ventilatory excursion. | NR/NR/35/35 | Age (Mean):77 yearsFemale: 64% Race: NR | Support: AF Beds  |
| Keogh, 200113UKPoor | Patient over 18 years oldPatients had to give consentLikely to stay in bed for at least 12 hours a dayTissue damage no greater than stage I PU | Patient with terminal illnessWeighing more than 120 kgPatients posing a manual handling risk who required an electric bed. | NR/100/100/70 (14 had PU on admission and were analyzed for treatment) | Age (Mean): 70 yearsFemale: 45% Race: NR | Support: Profiling Bed  |
| Makhsous, 200914USFair | Wheelchair user with SCI Stage II or III PUs in sacral and/or ischial areaAble to independently use manual or powered wheelchairSitting tolerance of at least 4 hours per day | Degenerative disorders of the spineHistory of injury or surgery of the pelvis, hip joint and the thigh; hip contracturesSevere pain, spasm, and psychological concerns preventing proper cooperation | NR/NR/44/44 | Age (Mean):43 years Female: 7%Race: NR | Support: Cyclic Pressure Relief Seats  |
| Malbrain, 201015BelgiumFair | ICU patients with high PU risk (Norton Score ≤to 8) or a PU who were going to require mechanical ventilation for an estimated duration of at least 5 days. | If consent was not obtained from closest relative or at least one of each of the two mattresses studied were not available when the patient was admitted. | NR/NR/16/16 | Age (Mean): 64 years Female: 50% Race: NR | Support: Reactive Air and Active Alternating Pressure |
| Mulder, 199416USPoor | PU Stage III or IV (Int'l Assoc. of Enterostomal Therapies)PU area between 1.5 cm x 1.5 cm and 10.0 cm x 20.0 cm | CarcinomatosisOsteomyelitis affecting the target PU Uncontrolled target PU infectionImmune deficiency disordersInadequate nutritional status | NR/NR/49/39 | Age (Mean): NRFemale: NRRace: NR | Support: LAL Beds |
| Munro, 198917USFair | Stage II or III PUExpected to remain in hospital at least 15 days | Stage IV PUWeight over 250 poundsExtremely malnourished (<70% of ideal body weight) or with serum albumin <2.1g /100 ml | NR/NR/40/40 | Age (Mean): 67Female: 0%Race: NR | Support: AF Bed  |
| Nixon, 200618UKGood | Sub group of large study of PU prevention and treatment55 years old or olderAdmitted to participating vascular, orthopaedic, medical or geriatric ward in previous 24 hoursExpected length of stay 7 or more daysConsented to participateRestricted mobility or Stage II PU | Stage III or higher existing PUPrior participation in trialElective surgery patients with planned post-op in ICU or admitted more than 4 days pre surgerySlept in chair at nightWeight more than 140 kg or less than 45 kg | 6155/1972/1972/1971 Full trial including prevention.NR/NR/113/113 for patients with PUs | Age (Mean):  75 yearsFemale: 64%Race: NR | Support: AP Overlay and Mattresses |
| Rosenthal, 200319USPoor | Stage III or IV PU on coccyx, trochanter, or ischial tuberositiesAble to sit up during previous 6 months with assistanceAlert | Previously enrolled in a trial to treat their current pressure PU; already using LAL or transfer to LAL was planned, skin grafting was planned within 1 week; they had an active sinus tract or fistula, nutrition was poor, as indicated by albumin levels below 3.0 g/dL; antibiotics were required to treat methicillin-resistant Staphylococcus aureus, vancomycin-resistant enterococci, or active skin infection; osteomyelitis was diagnosed; body weight was below 60 kg; patients were unable to flex both hip and knee past 90 degrees. Further, persons with sacral PU were excluded from the study because the sacral area is suspended above the generic total contact seat and hence is not in contact with the seat. | NR/NR/207/203 | Age (Mean): 70 yearsFemale: NRRace: NR | Support: Generic Total Contact Seat  |
| Russell, 2000(a)20Russell, 2000(b)21UKFair | Stage II or higher PU (Torrance grading scale) | Unwilling to participateRandomized equipment not availablePrevious inclusion in trial and readmittedWeighed more than 25 stone | NR/NR/183/112 | Age (Mean): 84 yearsFemale: NRRace: NR | Support: AP Beds |
| Russell, 200322UKFair | Admitted between April 2001 and April 2002Stage I PU or above on EPUAP | Unwilling to participate Previously in trialObese | NR/NR/199/158 | Age (Mean): 80 years Female: 54% Race: NR | Support: AP vs. Fluid Overlay |
| Strauss, 199123USFair | 16 years or olderStage 3 or 4 PU Future PU-related hospitalization expectedSeverely limited mobilityAdequate social support to use home AF therapyLikely to live one year or more; Out of hospital at least 3 weeks; Medical provider willing to closely manage care in home | Febrile or septic or otherwise required immediate hospitalization PU on radiated skin | NR/112/97/69 | Age (mean): 64 yearsFemale: 49% Race: NR | Support: AF Beds |

| **Evidence Table 1a. Support Trials, continued** |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author, yearCountryOverall Quality Rating** | **Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)** |  **Treatment A** | **Treatment B** | **Treatment C** | **Outcomes: Complete Wound Healing** | **Outcomes: Wound Surface Area** | **Outcomes: Healing Time** | **Outcomes: Pain** |
| Allman, 19871USGood | Stage I, II, III, IV, and unstageableTreatment A:Superficial-Epidermis: 13% (4)Superficial- Dermis: 39% (12)Deep-Subcutis: 29% (9)Deep-Bone/Muscle: 6% (2)Deep-Eschar: 13% (4)Treatment B:Superficial-Epidermis: 12% (4)Superficial- Dermis: 47% (16)Deep-Subcutis: 32% (11)Deep-Bone/Muscle: 3% (1)Deep-Eschar: 6% (2) | AF bed with positioning every 4 hours from 0700 hours to 2300 hours.  | Alternating air mattress covered by a foam pad with repositioning every 2 hours and elbow or heel pads as needed. |  NA | Patients with one or more healed sores during studyTreatment A: 65% (20)Treatment B: 44% (15) p=0.10 | Change in total surface area, cm2Median (Range)Treatment A: -1.2 (-38.0 to +15.5)Treatment B: + 0.5 (-55.1 to +94.7)p=0.0150% reduction in total surface areaTreatment A: 29% (9)Treatment B: 24% (8)p=0.64 | NR | Change in pain intensity from baselineTreatment A:Decreased: 62% (8) No change: 38% (5) Increased: 0 Treatment B:Decreased: 29% (4)No change: 50 (7)Increased: 21% (3)p=0.01Change in comfort from baselineTreatment AIncreased: 62% (8) No change: 31% (4) Decreased: 8% (1) Treatment B:Increased: 23% (3)No change: 31% (4)Decreased: 46% (6)p=0.04 |
| Branom, 20012USPoor | Treatment A:Stage III: 30% (3) Stage IV: 70% (7)Treatment B:Stage III: 25% (2)Stage IV: 75% (6)Staging system not cited | Non-powered air mattress with foam overlay  | LAL mattress |  NA | NR | At 3 WeeksTreatment A: Mean Amount Closed (cm2): 17.0, Mean % Closed: 43%Treatment B: Mean Amount Closed (cm2): 17.1, Mean % Closed: 22%At 8 WeeksTreatment A: Mean Amount Closed (cm2): 25.8Mean % Closed: 60%Treatment B: Mean Amount Closed (cm2): 22.2Mean % Closed: 40% | At 3 WeeksTreatment A:Rate of Closure per Week (cm2): 5.7 % Closed per Week: 14.4%Treatment B:Rate of Closure per Week (cm2): 5.7 % Closed per Week: 7.2%At 8 WeeksTreatment A:Rate of Closure per Week (cm2): 3.5 % Closed per Week: 9.0%Treatment B:Rate of Closure per Week (cm2): 2.8 % Closed per Week: 5.0% | NR |
| Caley, 19943USPoor | NR | LAL Bed  | LAL overlay  |  NA | NR | Change in Surface AreaMean, cm2 Treatment A: 3.8 Treatment B: 10.2 p=0.06 Perimeter average of initial and final, cmMean (Range)Treatment A: 20.0 Treatment B: 23.7 p=0.06 | NR | NR |
| Clark, 19974UKFair | Treatment A: Stage II: 50% (7)Stage III: 14% (2)Stage IV: 36% (5)Sacrum: 93% (13)Ischial: 7% (1)Treatment B:Stage II: 64% (7)Stage III: 9% (1)Stage IV: 27% (3)Sacrum: 91% (10)Ischial: 9% (1) | AP cushion with 4 cells | Static air filled cushion  |  NA | Treatment A: 21% (3)Treatment B: 45% (5)p=NS | Mean Reduction in Area per Day(Stage II only)absolute change: mean Treatment A: 0.13 Treatment B: 0.27  | NR | NR |
| Day, 19935USPoor | Treatment A:Stage II: 57% (25)Stage III: 14% (6)Stage IV: 25% (11)Unstageable: 5% (2)Treatment B: Stage II: 59% (23)Stage III: 21% (8)Stage IV: 10% (4)Unstageable: 10% (4) | Air-suspension bed  | Foam overlay  |  NA | NR | Initial/ Ending Mean Area in cm2 by StageStage IITreatment A: 12.7 /7.3 Treatment B: 10.0/5.3Stage III and IVTreatment A: 51.8/37.1Treatment B: 13.7/12.4p>0.05 | NR | NR |
| Devine, 19956ScotlandFair | Median Initial Stage, rangeTreatment A: 3 (2-5)Treatment B: 3 (2-5)Location (total population):Sacrum/buttocks: 59%Heels: 20%Trochanter: 17%Others: 5% | AP bed  | Airwave bed |  NA | Treatment A: 64% (10)Treatment B: 36% (5)p=NS | Median Reduction per Day cm2Treatment A: 0.089Treatment B: 0.107p=0.92 | NR | NR |
| Evans, 20007Land, 20008UKGood | HospitalTreatment A:Stage II: 43% (3) Stage III: 57% (4)Sacrum: 47% (4)Buttock: 0Heel: 53% (3)Treatment B:Stage II: 40% (2)Stage III: 60% (3)Sacrum: 40% (2)Buttock: 20% (1)Heel: 40% (2)Nursing HomeTreatment A:Stage II: 10% (1)Stage III: 70% (7)Stage IV: 20% (2)Sacrum: 20% (2)Buttock: 10% (1)Heel: 60% (6)Malleolus: 10% (1)Treatment B:Stage II: 20% (2)Stage III: 40% (4)Stage IV: 40% (4)Sacrum: 50% (5)Buttock: 0Heel: 40% (4)Malleolus: 10% (1) | AP mattress | Other brands of AP mattresses |  NA | NR | Median Reduction per Day (range)Hospital, Treatment A: 0.12 cm2 (0-0.21cm2)Treatment B: 0.08cm2 (0.04-0.33cm2)p=NSNursing HomeTreatment A: 0.11 cm2 (0.04-0.41cm2)Treatment B: 0.05cm2 (0-0.48cm2)p=NSMedian Relative % reduction per Day (range)HospitalTreatment A: 2.44% (0-7.14%)Treatment B: 1.34% (1.11-2.88%)p=NSNursing HomeTreatment A: 1.57% (0.45-5.00%)Treatment B: 0.99% (0-2.54%)p=NS | NR | NR |
| Ferrell, 19939USGood | Stage (Shea scale)Treatment A:Stage II: 58% (25)Stage III/IV: 42% (18)Treatment B:Stage 2: 66% (27)Stage III/IV: 34% (14)Deep Ulcers | LAL Bed  | Foam convoluted mattress (10 cm) overlying a hospital mattress.  |  NA | Treatment A: 60% (26)Treatment B: 46% (19) p=0.19 | Decrease in Size, mm2 per DayMedian (25th, 75th percentile) All PUsTreatment A: 9.0 (4.0, 19.8) Treatment B: 2.5 (0.5, 6.5) p=0.0002 | NR | NR |
| Groen, 199910HollandFair | Stage III or IV was an inclusion criteria | High Quality Foam Replacement Mattress  | Water mattress  |  NA | Percent completely healed at four weeksA. Treatment A: 45%B. Treatment B: 48%p=NS | NR | NR | Reported as complicating factor: see harms |
| Izutsu, 199811JapanPoor | Average Grade:Treatment A: II Treatment B: III  | Rolling air cushion bed  | Conventional bed with their positions being changed every 2 hours |  NA | NR | Wound Area Reduction: No significant difference (p=NR) | NR | NR |
| Jackson, 198812USPoor | NR | Air-Fluidized mattress | A variety of non air-fluidized devices were used, including a non alternating air mattress |  NA | NR | Patients Experiencing Decrease in Ulcer Area:Treatment A: 60% (9)Treatment B 45% (9).p=NR | NR | NR |
| Keogh, 200113UKPoor | Treatment A: Stage I: 11.4% (4) Treatment B:Stage I: 28.5% (10)  | Profiling Bed | Conventional Bed |  NA | Treatment A:100% (4)Treatment B: 20% (2) p=NR | NR | NR | NR |
| Makhsous, 200914USFair | Treatment A: Stage II: 55% (12)Stage III: 45% (10)Treatment B:Stage II: 43% (9)Stage III: 57% (13)  | Wheelchairs with a cyclic pressure-relief seating system | Regular wheelchairs |  NA | NR | Reduction in Wound Area:Treatment A: 45%Treatment B: 10%p<0.001Probability to achieve 30% wound closure at 30 days:Treatment A: 0.727Treatment B: 0.364 p=0.007 | Median Time 30% Wound Reductionin DaysTreatment A: 25Treatment B: >30 p=0.007 | NR |
| Malbrain, 201015Belgium Fair | PU at admission.Treatment A:Category I: 50% (5)Category II: 30% (3)Category III: 20% (2)Treatment B: Category I: 20% (2)Category II: 20% (2)Category III: 0 | AP mattress (Nimbus 3) | Reactive low-pressure mattress  |  NA | NR  | Change in surface area (cm2)Treatment A:-2.1Treatment B: 25.8 p=0.05 | NR | NR |
| Mulder, 199416USPoor | Treatment A:Stage III: 77% (24)Stage IV: 23% (7)Sacral: 48% (15)Trochanter: 29% (9)Ischial: 16% (5)Heel: 3% (1)Ankle: 3% (1)Treatment B:Stage III: 72% (13)Stage IV: 28% (5)Sacral: 50% (9)Trochanter: 28% (5) Ischial: 22% (4)Heel: 0Ankle: 0(International Association of Enterostomal Therapists staging system) | LAL Bed  | Foam Overlay  |  NA | Treatment A: 16% (5) in treatment B: 17% (3) p=NR | Decrease in ulcer area was 77% greater in treatment A vs. treatment B p=0.042 | NR | NR |
| Munro, 198917USFair | Total Population:Stage II: 52% (21) Stage III: 48% (19) | Air fluidized bed  | Standard hospital bed |  NA |  NR | Mean ulcer size shrank in treatment A and expanded in treatment B. p=0.05 |  NR | Pain scores fell over time in treatment A and Treatment B: p=0.359 |
| Nixon, 200618UKGood | Stage II Only | AP Mattress Overlay | AP Mattress Replacement |  NA | Treatment A: 34% (20)Treatment B: 35% (19) | Mean Absolute changeTreatment A: 1.0 Treatment B: 2.0 Mean Percentage changeTreatment A: -35 Treatment B: 34.4  | Median Time to Healing: Treatment A: 20 days Treatment B: 20 days p=0.86 | NR |
| Rosenthal, 200319USPoor | Stage III and IV | Generic Total Contact Seat | LAL Bed | Bed Overlay | NR | NR | Median Time to Total Healing: Treatment A: 3.33 monthsTreatment B: 4.38 monthsTreatment C: 4.55 months | NR |
| Russell 2000(a)20Russell 2000(b)21UKFair | Average Ulcer Severity Treatment A: 2.46 Treatment B: 2.57 | AP Bed and Cushion (Nimbus 3 and Aura Cushion) | AP Bed and Cushion (Pegasus Cairewave and Proactive Seating cushion) |  NA | NR | Mean Linear Growth Rate of Wound Edge (area change/ circumference/ time increment) (mm/24 hours):Treatment A:Stage IIa: 1.50Stage IIb: 0.04Stage III +: excluded due to insufficient dataTreatment B:Stage IIa 0.17Stage IIb -0.84Stage III +: excluded due to insufficient datap=NS | NR | NR |
| Russell, 200322UKFair | NR | AP mattress | Fluid overlay system |  NA | NR | NR | NR | NR |
| Strauss, 199123USFair | Stage III and IV | AF Bed  | Conventional treatment. Included AP beds, air, water and high density foam. |  NA | Treatment A: 62% (29) healed to Stage 2 or better and were removed from treatment Treatment B: NR  | NR | Mean Days to Heal to Stage II or Better: Treatment A:93 Treatment B: NR | NR |

| **Evidence Table 1a. Support Trials, continued** |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, yearCountryOverall Quality Rating** | **Outcomes: Infection Rate** | **Outcomes: Osteomyelitis** | **Outcomes: Recurrence Rate** | **Other Outcomes: Specify** | **Timing: Duration of Followup** | **Setting** |
| Allman, 19871USGood | NR | NR | NR | Patients who Improved: Treatment A: 62%Treatment B: 29% p=0.05Odds of improvement on Treatment A compared to Treatment B:5.6  | Weekly from enrollment until death or discharge from hospitalMedian: 13 daysRange: 4 to 77 days | Hospital |
| Branom, 20012USPoor | NR | NR | NR | Goals for Treatment vs. Results (at admission goal was classified as progressive closure, prepare for flap or maintenance)Treatment A vs. LALAchieved: 70% (7)Exceeded: 30% (3)Not achieved: 0%Treatment B:Achieved: 50% (4)Exceeded: 13% (1)Not achieved: 37% (3) | 8 weeks | Acute care with specialty in ventilator and sub-acute center |
| Caley, 19943USPoor | NR | NR | NR | NR | 1 month or until hospital discharge. | Hospital |
| Clark, 19974UKFair | NR | NR | NR | Stage III and IV onlyMean Change in Volume (cm3):Treatment A:0.56 Treatment B: 0.49% Change in Volume per Day:Treatment A: 1%Treatment B: 0.7%  | Mean Days of FollowupTreatment A: 58.64 Treatment B: 43.73 p=NS | Hospital and nursing homes |
| Day, 19935USPoor | NR | NR | NR | Mean of Weekly Patient Assessments of ComfortTreatment A: 4.1Treatment B: 3.7p>0.05Note: most patients unable to report | Assessed weekly until discharge. | Hospital |
| Devine, 19956ScotlandFair | NR | NR | NR | Median, range (10 point scale)How comfortable was the mattress?Treatment A: 8 (5-10)Treatment B: 8 ( 3-10)How well did you sleep?Treatment A: 8 ( 4-10)Treatment B: 8(7-10)Many patients unable to report | Followed for 4 weeks after enrollment. | Nursing home/Long-term care |
| Evans, 20007Land, 20008UKGood | NR | NR | NR | Median weekly comfort rating (5 point scale)Hospital:Treatment A: 5Treatment B: 4p=0.006Nursing Home:Treatment A: 5Treatment B: 4p=0.002 | Hospital: Until death, discharge, or healingNursing Home:Until death, hospitalization, healing, or completion of study period.  | Hospital and nursing home |
| Ferrell, 19939USGood | NR | NR | NR | ImprovementChange in StagesMedian (25th, 75th percentile)Shea scaleTreatment A: 2.0 (0, 2)Treatment B: 1.0 (0,2) p<0.05Sessing scaleMedian (25th, 75th percentile) Treatment A: 3.0 (1,3)Treatment B: 1.0 (0,3) p<0.01Cure Probability ratio= Cox hazard ratio (probability of cure with Low-Air Loss divided by the probability of cure with foam for subjects under each condition for the same period of time.Ratio (95% confidence level) p valueAll PU 2.66 (1.34-5.17) p=0.004Superficial 2.60 (1.24-5.41) p=0.01Deep 2.97 (0.61-14.5 p=0.18 | Until healing, death, transfer, withdrawal, or protocol deviationNumber of Followup Days,Median (25th, 75th percentile):Treatment A: 33 (15, 60)Treatment B: 40 (21.5, 90.5) p=0.56 | Nursing home/LTC |
| Groen, 199910HollandFair | NR | NR | NR | NR | Four weeks from initial assessment and assignment | Nursing home/LTC |
| Izutsu, 199811JapanPoor | NR | NR | NR | Improvement in StageTreatment A: Stage improved from 2.8 to 2.0 p<0.01 after three months Treatment B: Stage changed from 3.0 to 3.2 p>0.5 after three months.  | 3 months | Nursing home/LTC |
| Jackson, 198812USPoor | NR | NR | NR | NR | Until discharge Median Days in Study:Treatment A: 20 daysTreatment B: 37.5 days | Hospital |
| Keogh, 200113UKPoor | NR | NR | NR | NR | 5 to 10 days. | Hospital |
| Makhsous, 200914USFair | NR | NR | NR | Percentage Improvement in PUSH score(mean):Treatment A: 21.9 Treatment B: 5.8 (9.2) p=0.003 | 30 days | Community |
| Malbrain, 201015BelgiumFair | NR | NR | NR | Change in PUSH score –Treatment A: 1Treatment B; 3.4p=0.01Change in Category (EPUAP)Treatment A: 0 Treatment B: 0.8p=0.03 | Followed until discharge. Mean was 11days | Hospital |
| Mulder, 199416USPoor | NR | NR | NR | NR | 12 weeks or until ulcer healed | Nursing home/Long-term care |
| Munro, 198917USFair |  NR | NR | NR | NR |  15 days | Hospital |
| Nixon, 200618UKGood | NR | NR | NR | NR | Until healing, discharge, or end of trial. | Hospital |
| Rosenthal, 200319USPoor | NR | NR | NR | NR | 6 months | Nursing home/Long-term care |
| Russell, 2000(a)20Russell, 2000(b)21UKFair | NR | NR | NR | NR | Until discharge or healing | Hospital |
| Russell, 200322UKFair | NR | NR | NR | Overall Ulcer Progress:Treatment A: Improved: 71% (60) No Change: 1% (1)Worse: 27% (22)Treatment B: Improved: 75% (56)No change: 4% (3)Worse: 21% (16)p=0.67Worst Ulcer Progress:Treatment A: Improved: 76% (63) No Change: 1% (1)Worse: 23% (19)Treatment B: Improved: 84% (63)No change: 5% (4)Worse: 11% (8)p=0.053 | Until dischargeAverage Length of Stay:Treatment A: 22.17 daysTreatment B: 20.05 days. p=0.23 | Hospital |
| Strauss, 199123USFair | NR | NR | 11% (5) returned to AF bed after recurrence of stage 3 or 4 PU | ImprovedReviewer 1 % (#)/ Reviewer 2 %/(#)Treatment A:91% (20) /82% (18)Treatment B: 62% (8)/77% (10)AF had 55% fewer hospital days and used fewer inpatient resources. | 36 weeks | Other |

| **Evidence Table 1a. Support Trials, continued** |  |  |  |  |  |  |  |  |
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| **Author, yearCountryOverall Quality Rating** | **Harms: Pain** | **Harms: Dermatologic Complication** | **Harms: Bleeding** | **Harms: Infection** | **Severe Adverse Events** | **Withdrawal due to Adverse Events** | **Overall Adverse Events Rate** | **Funding Source** |
| Allman, 19871USGood | NR | New skin breakdownTreatment A 29%:(9)Treatment B: 44% (15)p=0.24 | Treatment A:Epitaxis: 3% (1)  | NR | NR | 4 withdrew due to difficulty in transferring from AF beds | 3% | Support Systems International, Inc. American Pharmaceutical Company (provided supplies), Henry J. Kaiser Family Foundation, Burroughs-Wellcome Scholar in Pharmacoepidemiology. |
| Branom, 20012USPoor | NR | NR | NR | NR | NR | NR | NR | Mattress supplied by Span-America Medical System |
| Caley, 19943USPoor | NR | NR | NR | NR | NR | NR | NR | NR |
| Clark, 19974UK.Fair | NR | NR | NR | NR | NR | 2 (1 from each group) withdrew due to malfunction of the cushion | NR | Raymor Ltd. supplied Quadtro cushions. Funding by Pegasus Airwave Ltd. |
| Day, 19935USPoor | NR | NR | NR | NR | NR | NR | NR |  Supported in part by funding from KCI |
| Devine, 19956ScotlandFair | NR | NR | NR | NR | NR | NR | NR | Supported by HNE healthcare grant for a part-time research nurse and provision of 3 Nimbus 1 mattresses |
| Evans, 20007Land, 20008UKGood | NR | NR | NR | NR | NR | NR | NR | Huntleigh Healthcare |
| Ferrell, 19939USGood | NR | NR | NR | NR | NR | Treatment B: 9 subjects were deviated from the protocol because their ulcers became substantially worse or failed to heal. | NR | Jewish Home for the Aged of Greater Los AngelesSepulveda VA Geriatric Research and Education Clinical CenterWest Los Angeles VA Geriatric Research and Education Clinical Center;Kinetic Concepts International |
| Groen, 199910HollandFair | Patients with Pain Treatment A:Week 0: 40%Week 1: 27%Week 2: 22%Week 3: 10%Week 4: 4%Treatment B:Week 0: 20%Week 1: 17%Week 2: 12%Week 3: 5%Week 4: 4% | Patients withEczema Treatment A:Week 0: 10%Week 1: 0%Week 2: 2%Week 3: 4%Week 4: 0%Treatment B:Week 0: 2%Week 1: 0%Week 2: 0%Week 3: 0%Week 4: 0%p=NSMacerationTreatment A:Week 0: 17%Week 1: 15%.0Week 2: 7%Week 3: 6%Week 4: 4%Treatment B:Week 0: 13%Week 1: 8%Week 2: 2%Week 3: 4%Week 4: 4%p=NS | NR | NR | NR | NR | NR | NR |
| Izutsu, 199811Japan Poor | NR | NR | NR | NR | NR |  None | NR | NR |
| Jackson, 198812USPoor | NR | NR | Among the 15 patients in the treatment group, all had some granulation or bleeding at both entry and endpoint. Among 17 patients in the comparator group with evolutions at both entry and endpoint, 14 continued to have granulation or bleeding. In one subject, granulation or bleeding ceased; in two subjects, granulation or bleeding developed. These findings were not statistically significant. | NR | NR | NR | NR | Support Systems International |
| Keogh, 200113UKPoor | NR | NR | NR | NR | NR | NR | NR | Huntleigh Healthcare Ltd |
| Makhsous, 200914US Fair | NR | NR | NR | NR | NR | NR | NR | National Institutes of Health and Falk Medical Research Trust |
| Malbrain, 201015BelgiumFair | NR | NR | NR | NR | NR |  None | NR | Beds, but no other support provided by manufacturers. No other funding source reported. |
| Mulder, 199416USPoor | NR | NR | NR | NR | NR | NR | NR | Kinetic Concepts, Inc. |
| Munro, 198917USFair | NR | NR | NR | NR | NR | NR | NR | Support Systems International |
| Nixon, 200618UKGood | NR | NR | NR | NR | NR | NR | Nine reported for the full trial, but not separated for the cohort with existing PU.These included 4 falls, 3 cot-side incidents, one contact dermatitis and one patient who caught back on bed rail when mattress deflated during transfer. | National Health Service, Health Technology Assessment |
| Rosenthal, 200319US. Poor | NR | NR | NR | NR | NR | 3 patients worsened on bed overlay and were withdrawn. | NR | Equipment loaned to hospital by manufacturers. |
| Russell, 2000(a)20Russell, 2000(b)21USFair | NR  | NR | NR | NR | NR | NR | NR | Equipment loaned to hospital by manufacturers |
| Russell, 200322UKFair | NR | NR | NR | NR | NR | NR | NR | KCI Medical  |
| Strauss, 199123USFair | NR | Treatment A: Dry skin: "several"; number NRDehydration: 1  | NR | NR | NR | NR | NR | Support Systems International |

Note: AF=air fluidized, AP=alternating pressure, LAL= low air loss.